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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/070102

Applicant's or agent's file reference 107111	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU01/01230	International Filing Date *(day/month/year)* 28 September 2001	Priority Date *(day/month/year)* 11 October 2000

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61N 1/05, A61F 11/04

Applicant

COCHLEAR LIMITED et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
9 November 2001	27 November 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **VINCE BAGUSAUSKAS** Telephone No. (02) 6283 2110

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU01/01230

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-31	YES
	Claims		NO
Inventive step (IS)	Claims	1-31	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-31	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The most relevant prior art are:-

D1) US 4046151
D2) US 4381013

The common characteristic features of claims 1, 2 and 31 are:-

- a plurality of electrodes
- first and second stiffening elements in combination bias the elongate member into a first insertion configuration
- wherein if the first or second stiffening element is "removed" the elongate member adopts the intermediate configuration.

Whilst D1 shows two electrodes it is shown that the stylets (stiffening elements) are inserted together into the elongate member. There is no clear disclosure that one stylet is removed to allow the elongate member to adopt an intermediate position (col 5, lines 47 to 65). Nor is there a clear disclosure of the stylets biasing the elongate member to adopt a first insertion configuration.

D2 discloses only one electrode. Nor is there a clear disclosure that the stiffening or first portion of the stylet is "removed" to allow the elongate member to adopt an intermediate configuration. The stiffening stylet appears to be used during an insertion phase to position the electrode into its final position. Nor is there a clear disclosure of the two stylet portions working in unison to bias the elongate member into a first insertion configuration. In fact from col 2, lines 38 to 44, the second portion of the stylet has no shape determination function at all.

Therefore it is considered that the invention claimed is not anticipated nor are they obvious in the light of the citations and thus the invention claimed is both novel and involves an inventive step.

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Published:
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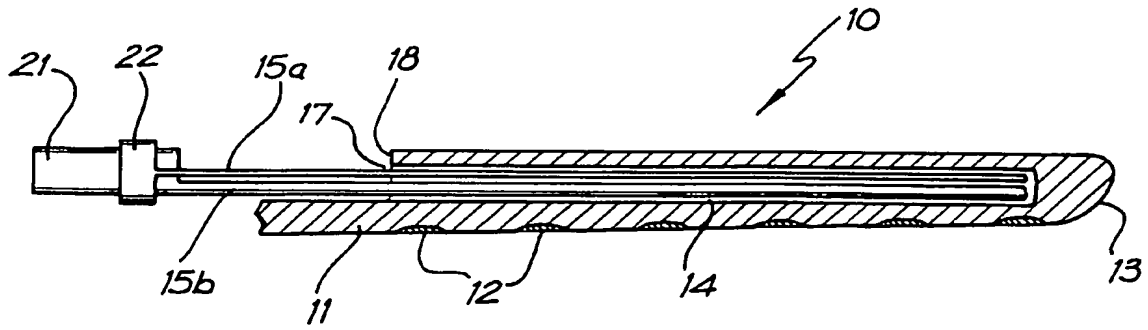
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DOUBLE STYLET INSERTION TOOL FOR A COCHLEAR IMPLANT ELECTRODE ARRAY



(57) Abstract: A cochlear implant electrode assembly device (10) comprising an elongate electrode carrier member (11), a first stiffening element (15a), and a second stiffening element (15b). The carrier member (11) is made of a resiliently flexible first material and has a plurality of electrodes (12) mounted thereon. The carrier member (11) has a first configuration selected to allow it to be inserted into an implantee's cochlea (30), a second configuration wherein it is curved in shape to match a surface of the cochlea (30), and at least one intermediate configuration between the first and second configurations. Both the first and second stiffening elements (15a, 15b) are made of a material relatively stiffer than said the material and in combination bias the elongate member into the first configuration. If either the first stiffening element (15a) or the second stiffening element (15b) are removed, the elongate member (11) adopts the at least one intermediate configuration.

WO 02/30507 A1

"Double stylet insertion tool for a cochlear implant electrode array"

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a stimulator/receiver unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the stimulator/receiver unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted stimulator/receiver unit typically included the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The external componentry of the cochlear implant has been traditionally carried on the body of the implantee, such as in a pocket of the implantee's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on a clothing lapel of the implantee.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the implantee. This unit has allowed the microphone, power unit and the speech processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

Together with improvements in available technology much research has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear

implant system that delivers electrical stimulation to the auditory nerve in a way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea-stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiola of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiola. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiola as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiola. Also, this way the delivery of the electrical stimulation to the auditory nerve is most effective as the electrode contacts are as close to the auditory nerves that are particularly responsive to selected pitches of sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it assumes this position upon or immediately following insertion into the cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape of the modiola and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this sense it has been found to be desirable for the electrode array be generally straight during the insertion procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In one case, a platinum wire stylet is used to hold a pre-curved electrode array in a generally straight configuration up until insertion. Following insertion, the platinum stylet is withdrawn allowing the array to return to its pre-curved configuration.

In another development, a bimetallic filament (such as nickel/titanium) or a shape memory alloy (eg. an alloy of nickel and titanium) is positioned in the electrode assembly and used to again hold a pre-curved electrode array in a generally straight configuration while the array is at about room temperature. On insertion into the body and exposure to body temperature, the filament or alloy bends into a pre-selected curved configuration.

In a still further arrangement, a longitudinal element that is arranged on one side of the array and constructed to change its dimension on insertion can be utilised. For example, the longitudinal element could include a hydrogel, such as polyacrylic acid (PAA) or polyvinyl alcohol (PVA), which expands after insertion by absorbing water from the cochlear fluid.

In developing such electrode array designs, it is of great importance that the design be constructed to minimise potential damage to sensitive structures in the cochlear on insertion and placement. Each of the above constructions suffer from a number of disadvantages in this regard.

Still further, it has been proposed to straighten pre-curved electrode arrays using inserted longitudinal elements or surrounding sheaths formed from bioresorbable materials that dissolve or soften on implantation. A disadvantage with use of such bioresorbable materials is that, due to the generally wet nature of the surgical environment, the polymer can dissolve or soften before the electrode array is appropriately positioned.

The present invention is directed to an electrode assembly adapted to overcome some of the difficulties of prior art electrode assemblies.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

an elongate member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's body, a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes, and at least one intermediate configuration between said first and second configurations, said elongate member being made of a resiliently flexible first material;

a first stiffening element; and

a second stiffening element;

wherein said first stiffening element and said second stiffening element in combination bias said elongate member into said first configuration and further wherein if either the first stiffening element or the second stiffening element is removed, the elongate member adopts said at least one intermediate configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

According to a second aspect, the present invention is a cochlear implant electrode assembly device comprising:

an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's cochlea, a second configuration wherein said elongate member is curved to match a surface of said cochlea, and at least one intermediate configuration between said first and second configurations, said elongate member being made of a resiliently flexible first material;

a first stiffening element; and

a second stiffening element;

wherein said first stiffening element and said second stiffening element in combination bias said elongate member into said first configuration and further wherein if either the first stiffening element or the second stiffening element is removed, the elongate member adopts said at least one intermediate configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration. The elongate member preferably has a first end that is firstly inserted into the implantee.

In a further embodiment, the elongate member can have a resiliently flexible tip member extending forwardly from the first end of the body. The tip member preferably has a distal end and a proximal end. The tip member can have a stiffness that is relatively less stiff than said stiffening element. The tip member can further be formed of a material that is substantially the same or the same stiffness as the body of the elongate member. In another embodiment, the tip member can be formed of a material that is relatively less stiff than at least a portion of the elongate member. In a further embodiment, the tip member can be formed of a material that undergoes a change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

In a further embodiment, the stiffness of the tip member can vary along at least a portion of its length from its distal end to its proximal end. In one embodiment, the stiffness of the tip member can vary over the entire length of the tip member or only a portion thereof. The stiffness can increase from the distal end to the proximal end. In one embodiment, the stiffness of the tip member over said portion or its length can increase gradually from its distal end towards to the proximal end. The increase in stiffness can be substantially smooth or increase in a stepwise fashion.

In a further embodiment, the tip member can be formed of the same material as the body of the elongate member. In another embodiment, the tip member can be formed of a different material to that of the body of the elongate member. The tip member can be comprised of an inner relatively stiff core of material having a tapered end, with at least the tapered end being overlaid by a relatively flexible material that extends beyond the tapered end of the core material so that the tip member undergoes a gradual decrease in flexibility in the region of the tapered end of the core moving away from the distal end.

The tip member can be formed separately to the body of the elongate member and mounted thereto. For example, the tip member can be adhered to the first end of the body of the elongate member. In another embodiment, the tip member can be integrally formed with the body of the elongate member. The tip member can be formed from a silicone material. In another embodiment, the tip member can be formed of an elastomeric material, such as polyurethane.

In another embodiment, the tip member can have a plurality of metallic particles dispersed therethrough. The metallic particles can be substantially evenly dispersed through the tip member. Alternatively, the metallic particles can be non-evenly dispersed throughout the tip member. In one embodiment, the metallic particles can increase in density away from the distal end towards the proximal end of the tip member. By varying the density of the metallic particles, it is possible to vary the relative stiffness of the tip member.

The metallic particles preferably comprise a biocompatible material, such as platinum. The particles can be substantially spherical or spherical. It will be appreciated that the particles can have other suitable shapes. In one embodiment, the particles can have a diameter between about 50μm and 100μm.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles also result in the tip member being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to monitor the placement and position of the tip member during or after insertion of the electrode array in the body, such as in the cochlea.

When the elongate member is in the first configuration, the tip member is preferably substantially straight and, more preferably, straight.

In a further embodiment, the tip member can be coated with a lubricious material. The lubricious material can be a bioresorbable or non-bioresorbable material.

The tip member can be formed from, or incorporate as a portion thereof, a bioresorbable material. The presence of the bioresorbable material preferably results in the flexibility of the tip member increasing on insertion of the tip member into the body, such as the cochlea. The bioresorbable material in the tip member can be selected from the group consisting of

polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

In another embodiment, the tip member can be formed from, or incorporate as a portion thereof, a polymeric coating which becomes softer, and so increases in resilient flexibility, in the presence of moisture or body heat.

The tip member preferably has a length from its distal end to its proximal end in the range of about 0.3 to 4mm, more preferably about 1.0 to 3mm. The diameter of the tip member can be substantially constant for a majority of its length or can vary in diameter. The tip member can be substantially cylindrical, cylindrical, or non-cylindrical for a majority of its length. At the distal end, the diameter preferably gradually decreases to form a rounded end. The maximum diameter of the tip member is preferably about 0.55mm.

In one embodiment, the tip member can be solid. In another embodiment, the tip member can have an external wall defining a cavity. In one embodiment, the cavity can have a diameter greater than that of the receiving portion of the body of the elongate member. In a further embodiment, the cavity can extend from the proximal end towards the distal end of the tip member. The cavity can decrease in diameter away from the proximal end. The cavity can be in communication with a distal end of the receiving portion of the body of the elongate member. In a further embodiment, the stiffening means can extend into the cavity when positioned within the device or assembly according to the respective aspects of the present invention. In a preferred embodiment, the tip member can move relative to the stiffening means when it extends into the cavity of the tip member.

In general, the tip could be made of a combination of materials arranged in a variety of geometries depending on the specific design goal. The outside shape and size of the tip can also be made in a variety of forms depending on the design goal.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as a flexible silicone elastomer Silastic. Silastic MDX 4-4210 is

an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate member can be formed from a polyurethane or other similar materials.

In one embodiment, the first and second stiffening elements can be formed of the same material.

In one embodiment, the first stiffening element is made of a material that is relatively stiffer than the first material. In another embodiment, the second stiffening element can be relatively stiffer than said first stiffening element. In another embodiment, the second stiffening element can be relatively less stiff than the first stiffening element. In a still further embodiment, the first and second stiffening element can have the same stiffness.

Where the second stiffening element is relatively stiffer than the first stiffening element, the relatively greater stiffness of the second stiffening element can be provided by its structural parameters. For example, the second stiffening element can have a greater diameter than the first stiffening element.

The first stiffening element and/or the second stiffening element can be formed of a bioresorbable material which dissolves or softens on exposure to a fluid. The stiffening elements can dissolve or soften on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid.

In a further embodiment, the bioresorbable material used for each stiffening element can be selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

In another embodiment, the first and/or second stiffening element can be formed from a non-bioresorbable material. In this embodiment, the first and/or second stiffening element can comprise a metallic or plastic stylet. The stylets can extend through a single lumen in the elongate member or through respective lumens in the elongate member. The respective stylets can be positioned side-by-side in the elongate member. In another embodiment, one of said stylets can extend through a lumen of another tubular stylet. For example, the second stylet may extend through a lumen of the first tubular stylet. The first tubular stylet can be cylindrical or have another cross-sectional shape.

In one embodiment, each stylet can be formed from a biocompatible material, such as a metal or metallic alloy. In a preferred embodiment, each metal stylet can be formed from platinum.

In a still further embodiment, the first and/or second stiffening element can be formed from a shape memory alloy or a heat sensitive material. For example, each stiffening element can be formed from an alloy of nickel and titanium, or a bimetallic element formed from two layers of different metals, that is shaped to take a straight or substantially straight configuration at room temperature but bend into another shape once it is exposed to body temperature.

In yet another embodiment, the first and second stiffening elements can be of different lengths. For example, it may be desirable for the relatively stiffer stylet to have a shorter length and the relatively more flexible stylet to have a longer length, or vice versa. It is also envisaged that each stylet can have the same length.

In one embodiment, the lumen for the stylet can be cylindrical and also can have an opening formed therein. In the case where one or two metal stylets are used, the stylet or stylets can extend out of the opening allowing the stylet or stylets to be manipulated and removed from the lumen during or following insertion of the device.

In the case where the first and/or second stiffening elements are formed of a bioresorbable material, the opening can act as a fluid ingress means allowing body fluids to enter the lumen on insertion of the device into an implantee.

Where the first stiffening element is a metallic or metallic alloy stylet, the second stiffening element can be formed of a bioresorbable material which dissolves or softens on exposure to a fluid, or vice versa. The bioresorbable material can dissolve or soften on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid.

In a further embodiment, the bioresorbable material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

The device can include an additional layer surrounding the elongate member. The additional layer can have a first rate of fluid ingress therethrough and have at least one fluid ingress means formed therein, the

rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer.

The fluid ingress means can comprise one or more openings in the additional layer. The openings can be closable. The openings can comprise slits in the additional layer. The slits can be formed to allow substantially the same or the same rate of ingress of fluid through the additional layer. In another embodiment, at least one slit can allow a different rate of progress of fluid through the additional layer compared to the other slits.

Where the first stiffening element is a metal or bioresorbable stylet, the second stiffening element can, in one embodiment, be formed from a shape memory or heat sensitive material, or vice versa. For example, the second stiffening element can be formed from a shape memory alloy or a bimetallic filament (such as nickel and titanium alloy or a bimetallic filament comprising respective layers of such metals) that is shaped to maintain the straight or substantially straight configuration of the elongate member at room temperature but will bend into another shape once exposed to body temperature.

Preferably, while both the first and second stiffening elements are in position within the device, it will retain the first configuration, which as discussed is preferably straight. If the first stiffening element is removed, whether it is by physical removal or otherwise, the remaining second stiffening element preferably has insufficient strength to retain the elongate member in its first configuration. It is preferred that the elongate member, on removal of the first stiffening element, will adopt an intermediate configuration in which the elongate member has at least some curvature. On subsequent removal of the second stiffening element, the elongate member is free to adopt the fully curved second configuration desired of an implant after insertion into the cochlea.

The present invention provides a surgeon with a means to at least partially control the rate of curvature formation in a cochlear electrode assembly during insertion into the cochlea. Such increased control is envisaged to reduce the potential for trauma to the cochlea caused by electrode assembly insertion.

In a further embodiment, at least a portion of an outer surface of the elongate member can have a coating of a lubricious material. In one

embodiment, a substantial portion or the entire outer surface of the elongate member can have a coating of the lubricious material.

In this embodiment, the lubricious material can be selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

According to a third aspect, the present invention is a cochlear implant electrode assembly device comprising:

an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's cochlea, a second configuration wherein said elongate member is curved to match a surface of said cochlea, and at least one intermediate configuration between said first and second configurations, said elongate member being made of a resiliently flexible first material;

a first stiffening element made of a material relatively stiffer than said first material; and

a second stiffening element that is relatively stiffer than said first stiffening element;

wherein said first stiffening element and said second stiffening element in combination bias said elongate member into said first configuration and further wherein if either the first stiffening element or the second stiffening element is removed, the elongate member adopts said at least one intermediate configuration.

In a further embodiment, the device can have one or more of the preferred features of the first and second aspects.

In a further aspect, the present invention comprises a method of implanting a tissue-stimulating device or cochlear electrode assembly device as defined herein in a body of an implantee.

In this aspect, the method can comprise a step of accessing the implantation site and then a step of inserting the device. Prior to insertion, the device is preferably substantially straight or straight. On insertion, the device can adopt an intermediate configuration (as defined herein). Either prior to full insertion or following full insertion, the device preferably adopts its second configuration.

Once implanted, the electrodes can receive stimulation signals from a stimulator means. The stimulator means is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator means or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator means.

The stimulator means is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator means is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver means and vice versa. The receiver means can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The

speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted stimulator/receiver means using the transmitter and receiver coils. The implanted stimulator/receiver means demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator means.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 is a simplified cross-sectional view of one embodiment of an electrode assembly according to the present invention depicted in its first configuration;

Fig. 2 is a simplified side elevational view of the electrode assembly of Fig. 1 depicted in an intermediate configuration;

Fig. 3 is a simplified side elevational view of the electrode assembly depicted in its second configuration; and

Figs. 4 and 5a-5d depict alternative tip structures for the electrode assembly depicted in Fig. 1.

Preferred Mode of Carrying Out the Invention

One embodiment of a cochlear implant electrode assembly according to the present invention is depicted generally as 10 in the drawings.

The depicted electrode assembly 10 has an electrical lead extending back to a stimulator/receiver housing. In considering this invention, it is to be understood that each electrode may have one or more wires (not depicted)

electrically connected thereto and extending from each respective electrode back through the lead to the stimulator/receiver.

The assembly 10 comprises an elongate electrode carrier member 11 having a plurality of electrodes 12 mounted thereon. For the purposes of clarity, the electrodes 12 depicted in Fig. 1 are not necessarily shown to scale. The electrodes 12 are not depicted in Figs. 2 and 3 for reasons of clarity.

The depicted elongate member 11 is preformed from a resiliently flexible silicone with memory and is preformed to a curved configuration suitable for insertion in the scala tympani of the cochlea. The elongate member 11 has a first end 13 that is firstly inserted into the implantee on insertion of the assembly 10.

As depicted in Fig. 4, the elongate member 11 can have a tip member 29 integrally formed with its first end 13. The tip 29 is formed from the same silicone used to fabricate the elongate member 11 and, in the depicted embodiment, the material of tip member 29 has a resilient flexibility equal to that of the material used for the carrier member 11..

Possible alternative constructions for the tip member 29 are provided in Figs, 5a-5d. As depicted in Fig. 5a, the tip member 70 can be solid and formed of an inner core 71 of relatively stiff material 71 and an outer layer 72 of relatively flexible material. The core 71 can taper in diameter over region 73 towards the distal end 21. The taper 73 causes the overall stiffness of the tip 70 to increase over the length of the taper 73 away from the distal end 21. The outer layer 72 can be formed of the same material as the remainder of the body of the elongate carrier member 11 or can be a different material.

As depicted in Fig. 5b, the tip member 40 can comprise a solid mass integrally formed to the first end 13 of the elongate carrier 11.

Still further and as depicted in Fig. 5c, the tip member 50 can comprise a solid mass 51 that is formed separately from the carrier member 11 and subsequently adhered thereto.

As depicted in Fig. 5d, the tip member 60 can comprise an elastomeric silicone material having a plurality of substantially spherical platinum particles 61 dispersed therethrough. The particles 61 have a diameter between about 50μm and 100μm. It will be appreciated that the particles 61 depicted in Fig. 5d are not drawn to scale.

In Fig. 5d, the particles 61 are depicted as substantially evenly dispersed through the tip member 60. In another embodiment, the particles

could be non-evenly dispersed through the tip member. For example, the particles could increase in density away from the distal end 21 towards the proximal end of the tip member 60. By varying the density of the platinum particles 61, it is possible to vary the relative stiffness of the tip member 60.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles 61 also result in the tip member 60 being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to either monitor the placement and position of the tip member 60 during or after insertion of the electrode array 10 in an implantee's cochlea.

Disposed within a substantially cylindrical lumen 14 is a substantially straight first platinum stylet 15a and a second platinum stylet 15b. The stylet 15a is relatively stiffer than the elongate carrier 11 but alone has a stiffness that is insufficient to retain the silicone elongate member 11 in the straight configuration depicted in Fig. 1. The second stylet 15b has a greater diameter than stylet 15a and is relatively stiffer than stylet 15a. Stylet 15b extends through opening 17 in lumen 14 to a handle 21 that can be gripped by the surgeon. Stylet 15a also extends out of opening 17 to a separate handle 22 mounted around and movable relative to handle 21. It should be noted that the stylets do not have to be the same length. It may be desirable to have a short relatively stiffer stylet and a long relatively more flexible stylet.

While stylets 15a,15b are each depicted as a platinum stylet, one of both stiffening elements could be provided by a bioresorbable stylet formed from a bioresorbable polyacrylic acid (PAA) that is adapted to dissolve or soften on exposure to cochlear fluids. It will be appreciated that a bioresorbable stylet could be formed from other suitable bioresorbable materials. A stylet made from a shape memory or heat sensitive material could also be utilised as stylet 15a and/or stylet 15b.

While the elongate member 11 is manufactured with a preformed curved configuration, the assembly 10 is typically delivered to a surgeon with the stylets 15a,15b in place. The placement of both of the stylets 15a,15b in the lumen 14 is sufficient to hold the elongate member 11 in the straight configuration depicted in Fig. 1.

On insertion of the device 10 into the scala tympani of the cochlea 30 and when the first end 13 reaches the back of the basal turn, the surgeon can grip handle 21 and withdraw the second relatively stiffer stylet 15b from the

lumen 14. As the stylet 15b is withdrawn, the elongate member 11 commences to re-curl (see Fig. 2) as the stiffness of the stylet 15a is insufficient to hold the elongate member 11 straight.

As the elongate member 11 curls, the surgeon can continue to further insert the curled assembly 10 into the scala tympani until the desired insertion is attained. Upon desired insertion, the platinum stylet 15a can be fully withdrawn through the opening 17 of the lumen 14, using handle 22. On full withdrawal of the stylet 15a, the elongate member 11 is free to adopt the spiral configuration depicted in Fig. 3 with the electrodes 12 facing the modiola within the cochlea 30 so that they are positioned as close as possible to the spiral ganglia thereof. It is also envisaged that during this final insertion, the platinum stylet 15a can be simultaneously withdrawn using handle 22, through the opening 17 of the lumen 14 to further assist with the ease of insertion.

The combination of the first and second stiffening elements 15a,15b provides the surgeon with greater control of the implantation procedure for the cochlear implant electrode assembly 10. The provision of greater control minimises the potential for trauma to the sensitive tissues inside the cochlea and also enhances the likelihood of successful placement of the assembly 10 at the first attempt.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. An implantable tissue-stimulating device comprising:

an elongate member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's body, a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes, and at least one intermediate configuration between said first and second configurations, said elongate member being made of a resiliently flexible first material;

a first stiffening element; and

at least a second stiffening element;

wherein said first stiffening element and said second stiffening element in combination bias said elongate member into said first configuration and further wherein if either the first stiffening element or the second stiffening element is removed, the elongate member adopts said at least one intermediate configuration.

2. A cochlear implant electrode assembly device comprising:

an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's cochlea, a second configuration wherein said elongate member is curved to match a surface of said cochlea, and at least one intermediate configuration between said first and second configurations, said elongate member being made of a resiliently flexible first material;

a first stiffening element; and

at least a second stiffening element;

wherein said first stiffening element and said second stiffening element in combination bias said elongate member into said first configuration and further wherein if either the first stiffening element or the second stiffening element is removed, the elongate member adopts said at least one intermediate configuration.

3. A device of claim 1 or claim 2 wherein the second configuration of the elongate member is curved.

4. A device of claim 3 wherein the elongate member adopts a spiral configuration when in the second configuration.

5. A device of claim 1 or claim 2 wherein the elongate member is preformed from a plastics material with memory and is preformed to the second configuration.

6. A device of claim 1 or claim 2 wherein the elongate member has a first end that is firstly inserted into the implantee.

7. A device of claim 1 or claim 2 wherein the first configuration is at least substantially straight.

8. A device of claim 1 or claim 2 wherein the elongate member is formed from a biocompatible material selected from the group comprising a silicone and a polyurethane.

9. A device of claim 1 or claim 2 wherein the first and second stiffening elements are formed of the same material.

10. A device of claim 1 or claim 2 wherein the first stiffening element is made of a material that is relatively stiffer than the first material.

11. A device of claim 10 wherein the second stiffening element is relatively stiffer than said first stiffening element.

12. A device of claim 11 wherein the second stiffening element has a greater diameter than the first stiffening element.

13. A device of claim 1 or claim 2 wherein at least the first stiffening element is formed of a bioresorbable material which dissolves or softens on exposure to a fluid.

14. A device of claim 13 wherein the bioresorbable material of said at least first stiffening element is selected from the group comprising polyacrylic acid

(PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

15. A device of claim 1 or claim 2 wherein at least the first stiffening element is formed from a non-bioresorbable material.

16. A device of claim 15 wherein at least the first stiffening element is a metallic or plastic stylet.

17. A device of claim 16 wherein the second stiffening element is a metallic or plastic stylet.

18. A device of claim 17 wherein the respective stylets extend through a single lumen in the elongate member.

19. A device of claim 17 wherein one of said stylets can extend through a lumen of the other stylet.

20. A device of claim 1 or claim 2 wherein the first and/or second stiffening element are formed from a shape memory material.

21. A device of claim 1 or claim 2 wherein the first and second stiffening elements are of different lengths.

22. A device of claim 1 or claim 2 wherein the first stiffening element is a metallic or metallic alloy stylet, and the second stiffening element is formed of a bioresorbable material which dissolves or softens on exposure to a fluid.

23. A device of claim 22 wherein the bioresorbable material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

24. A device of claim 1 or claim 2 wherein the device includes an additional layer surrounding the elongate member, the additional layer having a first rate of fluid ingress therethrough and have at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid

ingress means being greater than the first rate of fluid ingress through the additional layer.

25. A device of claim 24 wherein the fluid ingress means comprises one or more slits in the additional layer.

26. A device of claim 1 or claim 2 wherein the first stiffening element is a metal or bioresorbable stylet and the second stiffening element is formed from a shape memory material.

27. A device of claim 1 or claim 2 wherein at least a portion of an outer surface of the elongate member has a coating of a lubricious material.

28. A device of claim 27 wherein the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

29. A device of claim 6 wherein a resiliently flexible tip member extends forwardly from the first end of the elongate member.

30. A device of claim 29 wherein the tip member has a plurality of metallic particles dispersed therethrough.

31. A cochlear implant electrode assembly device comprising:

an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's cochlea, a second configuration wherein said elongate member is curved to match a surface of said cochlea, and at least one intermediate configuration between said first and second configurations, said elongate member being made of a resiliently flexible first material;

a first stiffening element made of a material relatively stiffer than said first material; and

a second stiffening element that is relatively stiffer than said first stiffening element;

wherein said first stiffening element and said second stiffening element in combination bias said elongate member into said first configuration and further wherein if either the first stiffening element or the second stiffening element is removed, the elongate member adopts said at least one intermediate configuration.

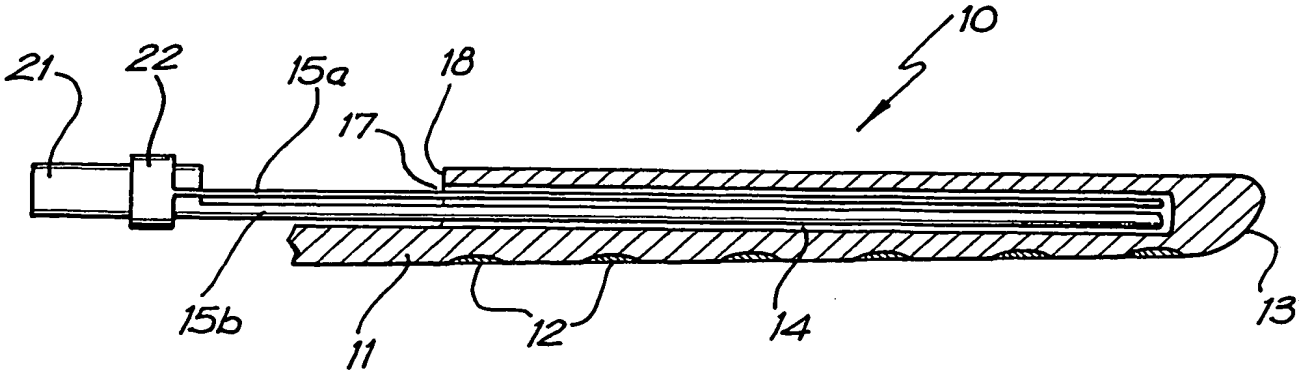


FIG. 1

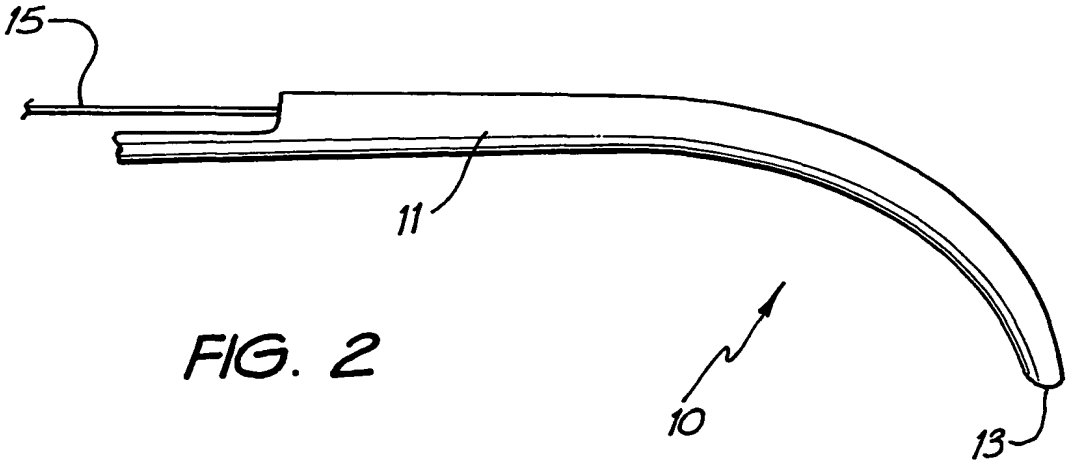


FIG. 2

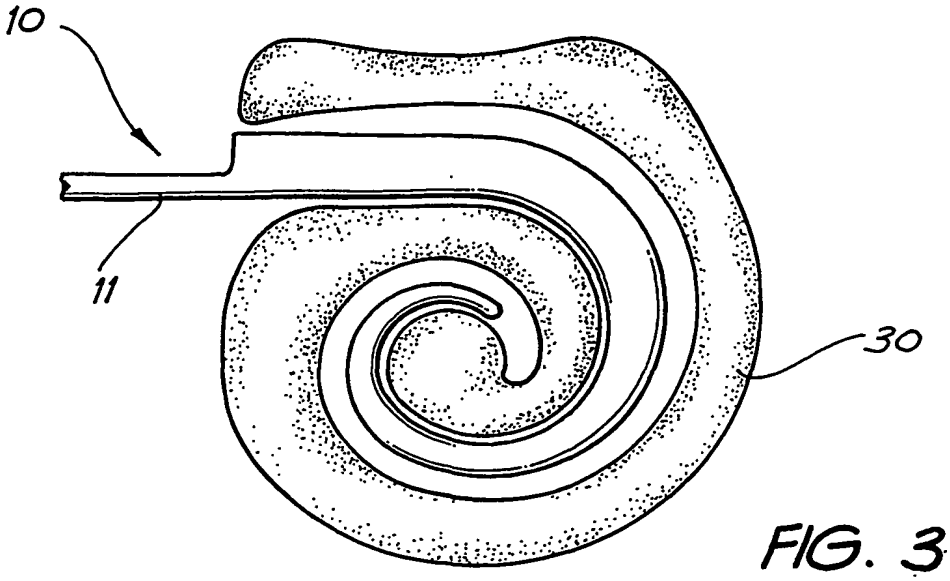


FIG. 3

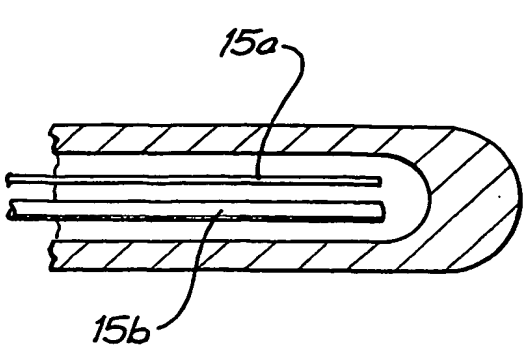


FIG. 4

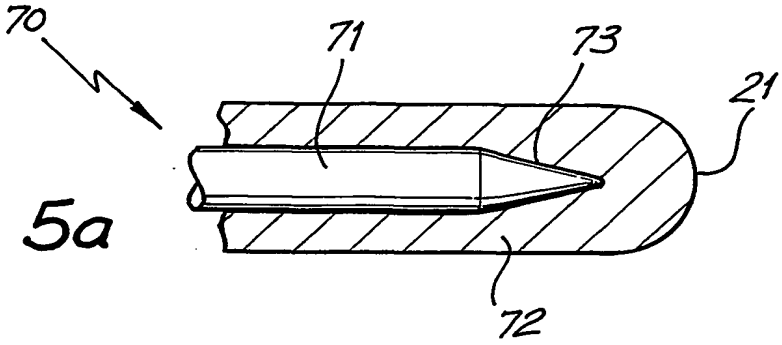


FIG. 5a

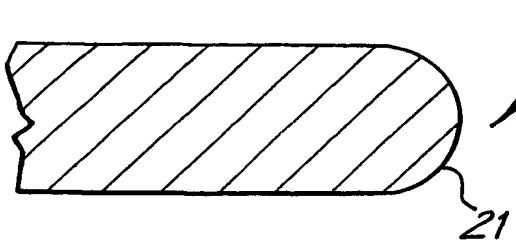


FIG. 5b

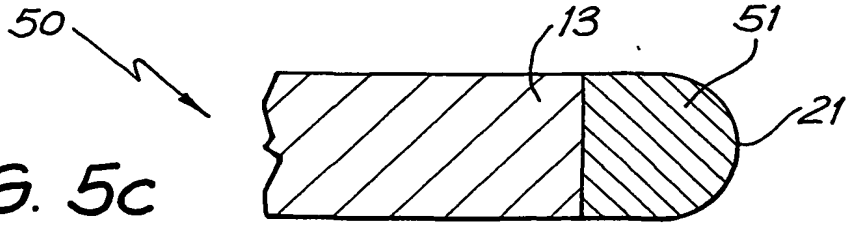


FIG. 5c

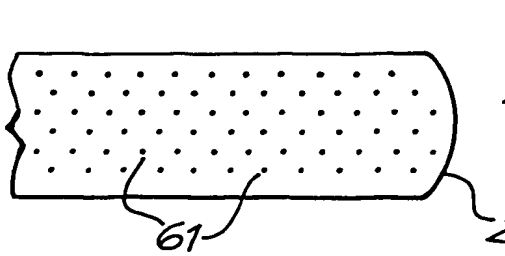


FIG. 5d

PARTICULARS FOR ENTRY INTO NATIONAL PHASE via Chapter II

Country	**United States of America**		**DUE DATE 11 APRIL 2003**	
Title	**Double stylet insertion tool for a cochlear implant electrode array**			
Our Reference	**109078**			
Applicant(s)/ Inventor(s)	**DADD, Fysh; DARLEY, Ian; GIBSON, Peter; PARKER, John; TREABA, Claudiu**			
Assignee	**COCHLEAR LIMITED, of 14 Mars Road, Lane Cove New South Wales 2066, Australia**			
Priority:	Application No	Country	Country Code	Date of Application
	PR0684	**Australia**	**AU**	**11 October 2000**
	PR0807	**Australia**	**AU**	**17 October 2000**
	PR1005	**Australia**	**AU**	**25 October 2000**
	PR1778	**Australia**	**AU**	**29 November 2000**
	Applicant	**COCHLEAR LIMITED**		
International Application	Application No	**PCT/AU01/01230**	Publication No.	**To be advised**
	Filing Date	**28 SEPTEMBER 2001**	Publication Date	**To be advised**
Demand Filed	Demand for International Preliminary Examination Filed **9 NOVEMBER 2001**			
Documents	**Enclosed are the following:-** -PCT Request (including specification as filed) -International Search Report together with Prior Art (Please lodge Prior Art with an Information Disclosure Statement) -Copies of documents cited in the specification, also for lodgement with the Information Disclosure Statement -PCT Demand - International Preliminary Examination Report			
	To follow:- - A copy of the published specification will follow as soon as it is received			
Entity Status	**Large Entity**			
Renewals	Renewals will be handled by our client's renewal payment service.			

BAL/ejp/a18pat050us

PCT

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 107111

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty

Box No. I TITLE OF INVENTION

Double stylet insertion tool for a cochlear implant electrode array

Box No. II APPLICANT ☐ This person is also inventor.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

COCHLEAR LIMITED
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Facsimile No.

Teleprinter No.

Applicant's registration No. with the Office

State *(that is, country)* of nationality: AU

State *(that is, country)* of residence: AU

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

DADD, Fysh
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Australia

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: AU

State *(that is, country)* of residence: AU

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

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☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet is not to be included in the request

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:
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- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: AU

State *(that is, country)* of residence: AU

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: AU

State *(that is, country)* of residence: AU

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:
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- ☒ applicant and inventor
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Applicant's registration No. with the Office

State *(that is, country)* of nationality: AU

State *(that is, country)* of residence: AU

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: AU

State *(that is, country)* of residence: AU

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. V **DESIGNATION OF STATES** *Mark the applicable check-boxes; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a):

Regional Patent

☒ **AP ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **MZ** Mozambique, **SD** Sudan, **SL** Sierra Leone, **SZ** Swaziland, **TZ** United Republic of Tanzania, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

☒ **EA Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ **EP European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, **TR** Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ **OA OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GQ** Equatorial Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line):*

☒	**AE** United Arab Emirates	☒	**GE** Georgia	☒	**MW** Malawi		
☒	**AG** Antigua and Barbuda	☒	**GH** Ghana	☒	**MX** Mexico		
☒	**AL** Albania	☒	**GM** Gambia	☒	**MZ** Mozambique		
☒	**AM** Armenia	☒	**HR** Croatia	☒	**NO** Norway		
☒	**AT** Austria	☒	**HU** Hungary	☒	**NZ** New Zealand		
☒	**AU** Australia	☒	**ID** Indonesia	☒	**PL** Poland		
☒	**AZ** Azerbaijan	☒	**IL** Israel	☒	**PT** Portugal		
☒	**BA** Bosnia and Herzegovina	☒	**IN** India	☒	**RO** Romania		
	.....	☒	**IS** Iceland	☒	**RU** Russian Federation		
☒	**BB** Barbados	☒	**JP** Japan		.....		
☒	**BG** Bulgaria	☒	**KE** Kenya	☒	**SD** Sudan		
☒	**BR** Brazil	☒	**KG** Kyrgyzstan	☒	**SE** Sweden		
☒	**BY** Belarus	☒	**KP** Democratic People's Republic	☒	**SG** Singapore		
☒	**BZ** Belize		of Korea	☒	**SI** Slovenia		
☒	**CA** Canada	☒	**KR** Republic of Korea	☒	**SK** Slovakia		
☒	**CH & LI** Switzerland and Liechtenstein	☒	**KZ** Kazakstan	☒	**SL** Sierra Leone		
☒	**CN** China	☒	**LC** Saint Lucia	☒	**TJ** Tajikistan		
☒	**CO** Colombia	☒	**LK** Sri Lanka	☒	**TM** Turkmenistan		
☒	**CR** Costa Rica	☒	**LR** Liberia	☒	**TR** Turkey		
☒	**CU** Cuba	☒	**LS** Lesotho	☒	**TT** Trinidad and Tobago		
☒	**CZ** Czech Republic	☒	**LT** Lithuania		.....		
☒	**DE** Germany	☒	**LU** Luxembourg	☒	**TZ** United Republic of Tanzania		
☒	**DK** Denmark	☒	**LV** Latvia	☒	**UA** Ukraine		
☒	**DM** Dominica	☒	**MA** Morocco	☒	**UG** Uganda		
☒	**DZ** Algeria	☒	**MD** Republic of Moldova	☒	**US** United States of America		
☒	**EE** Estonia		.....	☒	**UZ** Uzbekistan		
☒	**ES** Spain	☒	**MG** Madagascar	☒	**VN** Viet Nam		
☒	**FI** Finland	☒	**MK** The former Yugoslav Republic	☒	**YU** Yugoslavia		
☒	**GB** United Kingdom		of Macedonia	☒	**ZA** South Africa		
☒	**GD** Grenada	☒	**MN** Mongolia	☒	**ZW** Zimbabwe		

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☒	**PH** Philippines	☐	.....	☐	.....		
☐	.....	☐	.....	☐	.....		

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Box No VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year*	Number of earlier application	Where earlier application is:		
		national application: country	regional application:* regional Office	international application: receiving Office
item (1) 11 October 2000 (11.10.00)	PR0684	Australia		
item (2) 17 October 2000 (17.10.00)	PR0807	Australia		
item (3) 25 October 2000 (25.10.00)	PR1005	Australia		
item (4) 29 November 2000 (29.11.00)	PR1778	Australia		
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as:

☒ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

**Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)).* .....

.....

Box No VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA)
(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA / .....

Request to use results of earlier search: reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*:

Date *(day/month/year)*	Number	Country *(or regional Office)*
20/12/00	00/2808	Australia

Box No VIII DECLARATIONS

The following **declarations** are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable checkboxes below and indicate in the right column the number of each type of declaration)*: Number of declarations

☐	Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐	Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐	Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐	Box No. VIII (iv)	Declaration of inventorship (only for purposes of the designation of the United States of America)	:
☐	Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

Box No IX CHECK LIST; LANGUAGE OF FILING

This international application **contains**:

(a) the following number of **sheets in paper form**:

request (including declaration sheets)	:	5
description (excluding sequence listing part)	:	17
claims	:	5
abstract	:	1
drawings	:	2
Sub-total number of sheets:	:	30
sequence listing part of description (actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below)	:	
Total number of sheets	:	30

(b) sequence listing part of description filed in **computer readable form**

(i) ☐ only (under Section 801(a)(i))
(ii) ☐ in addition to being filed in paper form (under Section 801(a)(ii))

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained *(additional copies to be indicated under item 9(ii), in right column)*:

.....

This international application is **accompanied** by the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*:

Number of items

1. ☒ fee calculation sheet :
2. ☐ original separate power of attorney :
3. ☐ original general power of attorney :
4. ☐ copy of general power of attorney; reference number, if any: .....:
5. ☐ statement explaining lack of signature
6. ☐ priority document(s) identified in Box No. VI as item(s): .....:
7. ☐ translation of international application into *(language)*:.....:
8. ☐ separate indications concerning deposited microorganism or other biological material :
9. ☐ sequence listing in computer readable form (indicate also type and number of carriers (diskette, CD-ROM, CD-R or other))
   (i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application) :
   (ii) ☐ *(only where check-box (b)(i) or (b)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter* :
   (iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing part mentioned in left column :
10. ☐ other (specify): .....:

Figure of the drawings which should accompany the abstract: Fig 1

Language of filing of the international application: English

Box No X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

BRETT LUNN
for and on behalf of F B Rice & Co

For receiving Office use only

1. Date of actual receipt of the purported international application:		2. Drawings:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		☐ received
4. Date of timely receipt of the required corrections under PCT Article 11(2):		☐ not received
5. International Searching Authority (if two or more are competent): ISA/	6. ☐ Transmittal of search copy delayed until search fee is paid	

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

Th[illegible]eet is [illegible]art of and does not count as a sheet of the inter[illegible]l application

For receiving Office use only

PCT

FEE CALCULATION SHEET
Annex to the Request

International Application No

Applicant's or agent's file reference 107111

Date stamp of the receiving Office

Applicant
Cochlear Limited et al

CALCULATION OF PRESCRIBED FEE

1. TRANSMITTAL FEE ..... $100.00 T
2. SEARCH FEE ..... $800.00 S

International search to be carried out by
(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

Where item (b) of Box No. IX applies, enter Sub-total number of sheets)
Where item (b) of Box No. IX does not apply, enter Total number of sheets)

b1 first 30 sheets $759.00 b1

b2 _____ (number of sheets in excess of 30) x _____ (fee per sheet) = _____ b2

b3 additional component (only if sequence listing part of description is filed in computer readable form under Section 801(a)(i), or both in that form and on paper, under Section 801(a)(ii)):
_____ (number of sheets) x _____ (fee per sheet) = _____ b3

Add amounts entered at b1, b2 and b3 and enter total at B $759.00 B

Designation Fees

The international application contains all designations.

6 (number of designation fees payable (*maximum 6*)) x $164.00 (amount of designation fee) = $984.00 D

Add amounts entered at B and D and enter total at I ..... $1743.00 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT *(if applicable)* ..... $120.00 P

5. TOTAL FEES PAYABLE.

Add amounts entered at T, S, I and P, and enter total in the TOTAL box $2763.00 TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

☐ authorization to charge deposit account (see below)
☐ postal money order
☐ cash
☐ coupons
☒ cheque
☐ bank draft
☐ revenue stamps
☐ other (*specify*):

AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT
(this mode of payment may not be available at all receiving Offices)

☐ Authorization to charge the total fees indicated above.
☐ *(This check-box may be marked only if the conditions for deposit accounts of the Receiving Office so permit)* Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.
☐ Authorization to charge fee for priority document.

Receiving Office: RO/.....
Deposit Account No:.....
Date:.....
Name:.....
Signature:.....

See Notes to the request form

The demand must be filed direct[illegible] competent International Preliminary Examining Authority o[illegible] two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant in the line below:

IPEA/_____

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference: 107111

International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/AU01/01230	28 September 2001	11 October 2000

Title of invention

Double stylet insertion tool for a cochlear implant electrode array

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

COCHLEAR LIMITED
14 Mars Road
Lane Cove New South Wales 066
Australia

Telephone No

Facsimile No.

Teleprinter No.

Applicant's registration No. with the Office

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AU	AU

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

DADD, Fysh
c/- 14 Mars Road
Lane Cove New South Wales 2066
Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AU	AU

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

DARLEY, Ian
c/- 14 Mars Road
Lane Cove New South Wales 2066
Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AU	AU

☒ Further applicants are indicated on a continuation sheet.

International application No.
PCT/AU01/01230

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet is not to be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GIBSON, Peter
c/- 14 Mars Road
Lane Cove New South Wales 2066
Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AU	AU

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

PARKER, John
c/- 14 Mars Road
Lane Cove New South Wales 2066
Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AU	AU

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

TREABA, Claudiu
c/- 14 Mars Road
Lane Cove New South Wales 2066
Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AU	AU

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

☐ Further applicants are indicated on another continuation sheet.

International application No.
PCT/AU01/01230

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is ☒ agent ☐ common representative

and ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.

☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

F B RICE & CO
605 Darling Street
BALMAIN NSW 2041
AUSTRALIA

Telephone No
(612) 9810 7133
Facsimile No.
(612) 9810 8200
Teleprinter No.

Agent's registration No. with the Office

☐ **Address for correspondence**: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments: *

1. The applicant wishes the international preliminary examination **to start on the basis of:**

☒ the international application as originally filed

the description ☐ as originally filed
☐ as amended under Article 34

the claims ☐ as originally filed
☐ as amended under Article 19 (together with any accompanying statement)
☐ as amended under Article 34

the drawings ☐ as originally filed
☐ as amended under Article 34

2. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3 ☐ The applicant wishes the start of the international preliminary examination **to be postponed** until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: .....

☒ which is the language in which the international application was filed.
☐ which is the language of a translation furnished for the purposes of international search.
☐ which is the language of publication of the international application.
☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby **elects all eligible States** *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes **not to elect:**

See Notes to the demand form

International application No.
PCT/AU01/01230

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:			For International Preliminary Examining Authority use only: received	not received
1. translation of international application	:	sheets	☐	☐
2. amendments under Article 34	:	sheets	☐	☐
3. copy of (or, where required, translation) of amendments under Article 19	:	sheets	☐	☐
4. copy of (or, where required, translation) of statement under Article 19	:	sheets	☐	☐
5. letter	:	sheets	☐	☐
6. other *(specify)*	:	sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. ☒ fee calculation sheet
2. ☒ original separate power of attorney
3. ☐ original general power of attorney
4. ☐ copy of general power of attorney: reference number, if any:
5. ☐ statement explaining lack of signature
6. ☐ sequence listing in computer readable form
7. ☐ other *(specify)*

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

Dr Brett Andrew Lunn
for and on behalf of F B Rice & Co

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:
2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):
3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. ☐ The applicant has been informed accordingly.
4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5
5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

See Notes to the fee calculation sheet